K032543

NOV 1 4 2003

510(k) Summary
for
Sirona Dental Systems
C8+ Dental Operative Unit with Accessories

1. SPONSOR

Sirona Dental Systems GmbH
Farbrikstrasse 31
64625 Bensheim
Germany

2. DEVICE NAME

Proprietary Name:	C8+ Dental Operative Unit
Common/Usual Name:	Dental Operative Unit
Classification Name:	Dental Operative Unit with Accessories

3. PREDICATE DEVICES

C8 Dental Operative Unit with Accessories, K983242

Spirit S1 Dental Operative Unit with Accessories, K962071

4. INTENDED USE

The C8+Dental Operative Unit with accessories is intended to supply power to and serve as a base for dental devices and accessories. This product includes a dental chair. The unit is intended for use in the dental clinic environment and used by trained dentists and/or dental technicians and assistants.

The C8+ Dental Operative Unit is offered with the optional Sivision 3 intraoral camera system, which is intended to provide the dentist and patient with intraoral video images to view the condition of the teeth and oral cavity.

5. DEVICE DESCRIPTION

The C8+ is a modification of the C8 Dental Operative Unit and includes some features previously available on the Spirit S1 Dental Operative Unit. The C8+ consists of the following major components:

- Patient Treatment Chair
- Dentist's Element
- Assistant's Element
- Water Unit with Cuspidor
- Overhead Dental Light

The C8+ can supply power to five (5) dental instruments, which may include an air water syringe, high and low speed turbines and electric motors, ultrasonic scalers, intraoral X -ray film viewer, fiber optic light instruments, dental curing light, water warmers, airscaler, and an air polisher. These accessories are not part of the C8+ dental operating unit 510(k). The C8+ also offers an optional built-in disinfection apparatus and an optional video system, SIVISION 3, which consists of an intraoral camera and a flat-screen LCD monitor.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Sirona Dental Systems C8+ Dental Operative Unit with Accessories is substantially equivalent to the Sirona Dental Systems Sirona C8, K983242, and the Spirit S1 Dental Operative Unit, K962071. The C8+ has the same intended use as the predicates in that they are all used to supply power to, and serve as a base for dental devices and accessories.

The technological characteristics of the proposed and predicate devices are the same in that they include similar components, and are similar in design, characteristics, and mode of operation. Both the proposed and predicate devices include a chair, dentist's instrument board, cuspidor, assistant's board, dental light and footswitches for control of the various components. The C8+ includes various options also offered on either the C8 or the Spirit S1. The C8+ also includes additional features that do not change the fundamental technology of the device or raise new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2003

Ms. Mary McNamara-Cullinane
Regulatory Affairs Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K032543
Trade/Device Name: Sirona Dental Systems C8+ Dental Operative Unit with Accessories
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: August 15, 2003
Received: August 18, 2003

Dear Ms. Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

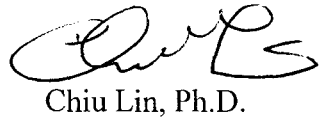
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032543

Device Name: Sirona Dental Systems C8+ Dental Operative Unit with Accessories

Indications for Use:

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The C8+ Dental Operative Unit is offered with the optional Sivision 3, an intraoral camera system intended to provide the dentist and patient with intraoral video images to view the condition of the teeth and oral cavity.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K032543

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)